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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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12/10/2004

Jianhua Feng

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EXAMINER

MACAULEY, SHERIDAN R

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

12/28/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/517,904	<b>Applicant(s)</b> FENG ET AL.	
	<b>Examiner</b> SHERIDAN R. MACAULEY	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7,8 and 10-23 is/are pending in the application.
- 4a) Of the above claim(s) 10-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5, 7 and 8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/4/2009</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

A response and amendment were received and entered on December 9, 2008. All evidence and arguments have been fully considered. Claims 1, 3-5, 7, 8 and 10-23 are pending. Claims 10-23 are withdrawn due to a prior requirement for restriction. Claims 1, 3-5, 7 and 8 are examined on the merits in this office action.

### ***Claim Objections***

Claim objections have been withdrawn due to applicant's amendment.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. The phrase "the measurable activity in the extract is at least 2000 times greater than a specific activity of PKB Ser 473 kinase activity in a crude extract" in claim 7 renders the claims indefinite because it is unclear how the "specific activity" in the crude extract relates to the "measurable activity" in the purified extract. Since the two types of activity are described in different terms, the claim could be interpreted as measuring two types of activities or measuring the activities using identical methods for comparison. To clarify this term, applicant is advised to specify in the claim how the activities are

measured and compared. For instance, if applicant intends to claim that the activity is measured using the same metric, it is suggested that applicant use the same term to describe the activity and include a statement such as "wherein the activity is measured by ..." As written, the metes and bounds of the claim would be unclear to one of ordinary skill in the art.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3-5, 7 and 8 are rejected under 35 U.S.C. 102(b) as anticipated by Brown (US 6,322,962), Joly et. al (US 6,342,495) or Cravatt et al. (US 2002/0040275) as evidenced by Toker et al. (J. Biol. Chem., 2000, 275:8271-4; cited in prior action). Claim 1 recites a cell-free composition comprising a complex which has a PKB Ser 473 kinase activity and an apparent molecular weight of 450-650 kDa. Claims 3 and 4 recite the composition of claim 1, wherein said complex comprises a protein having a molecular weight of 48 kDa and a protein having a molecular weight of 58 kDa as estimated by SDS gel electrophoresis. Claim 5 recites a purified PKB Ser 473 kinase protein complex, has PKB Ser 473 kinase activity and an apparent molecular weight of 450-650 kDa when fractionated by gel filtration chromatography. Claim 7 recites a purified cell extract that has measurable PKB Ser 473 kinase activity in 0.2 micrograms

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of protein when detected in a kinase assay in which a PKB peptide substrate is phosphorylated with  $^{32}\text{P}$  labelled phosphate, wherein the kinase elutes with an apparent molecular weight of 450-650 kDa when fractionated by gel filtration chromatography.

Claim 8 recites the purified cell extract of claim 7, wherein the kinase elutes with an apparent molecular weight of 550 kDa when fractionated by gel filtration chromatography.

6. Brown (col. 9, lines 58-64), Joly (col. 13, lines 12-19) and Cravatt (p. 20, par 182) each teach compositions comprising the membrane fraction of HEK 293 cells. The membrane preparations of the references are purified (i.e. they have been separated from other cellular components) and inherently cell-free. As evidenced by Toker, the HEK 293 cells would inherently possess PKB Ser 473 kinase activity (abstract, p. 8273, par. 3, fig. 3). Because these preparations are prepared in the same way as those disclosed in the instant application, e.g., the HEK 293 cells are lysed and the membrane fraction has been prepared (see, for example, p. 12, par. 2-4 or the instant specification), they would inherently comprise a complex with the claimed activity and molecular weight and comprise the proteins with the claimed molecular weights.

7. The claimed functions, characteristics, and/or traits must be inherent to the reference composition. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. Thus the claiming of a new use, functions or unknown property that is inherently present in the prior art does not necessarily make the claim patentable (See MPEP 2112).

8. Therefore, the cited references anticipate all of the limitations of the claims.

### ***Response to Arguments***

9. Applicant's arguments filed September 22, 2009 have been fully considered but they are not persuasive. Applicant argues that the cited references do not render obvious the claimed invention because the references do not disclose a "complex which has PKB Ser 473 activity and an apparent molecular weight of 450-650 kDa." It is noted, however, that the Toker reference is relied upon to demonstrate that a cell free extract from HEK293 cells possesses PKB Ser 473 activity, regardless of whether the specific protein taught by the reference has that activity. As further evidenced by applicant's disclosure, a cell-free extract of HEK293 cells possesses PKB Ser 473 activity and contains a complex with the molecular weight recited in the claims. Therefore, a reference that teaches a cell free extract of HEK293 cells inherently meets the limitations recited in the claims. Although applicant argues that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the complex has been purified from the cell-free extract) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore, applicant's arguments have been fully considered, but they have not been found to be persuasive.

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM

/Ruth A. Davis/

Primary Examiner, Art Unit 1651